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Medical electrical equipment —

Part 2-70:

Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment

Appareils électromédicaux —

Partie 2-70: Exigences particulières pour la sécurité de base et les performances essentielles de l'équipement de thérapie respiratoire pour l'apnée du sommeil

Reference number
ISO 80601-2-70:2015(E)



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Contents

Page

Foreword	vi
Introduction	viii
201.1 Scope, object and related standards.....	1
201.1.1 Scope.....	1
201.1.2 Object	2
201.1.3 Collateral standards.....	2
201.1.4 Particular standards.....	2
201.2 Normative references.....	3
201.3 Terms and definitions	5
201.4 General requirements	6
201.4.3 ESSENTIAL PERFORMANCE	6
201.4.3.101 Additional requirements for ESSENTIAL PERFORMANCE	6
201.4.6 ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT	6
201.5 General requirements for testing of ME EQUIPMENT.....	6
201.5.101 Additional requirements for general requirements for testing of ME EQUIPMENT	7
201.5.101.1 Gas flowrate and pressure specifications.....	7
201.5.101.2 SLEEP APNOEA BREATHING THERAPY EQUIPMENT testing errors	7
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	7
201.7 ME EQUIPMENT identification, marking and documents	7
201.7.1.2 Legibility of markings	7
201.7.2.4.101 Additional requirements for ACCESSORIES	7
201.7.2.13.101 Additional requirements for physiological effects	7
201.7.17.101 Additional requirements for protective packaging.....	8
201.7.2.101 Additional requirements for marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts.....	8
201.7.4.3 Units of measurement.....	8
201.7.9.1 Additional general requirements	9
201.7.9.2.1.101 Additional general requirements	9
201.7.9.2.2.101 Additional requirements for warnings and safety notices.....	9
201.7.9.2.9.101 Additional requirements for operating instructions.....	10
201.7.9.2.14.101 Additional requirements for ACCESSORIES, supplementary equipment, used material	10
201.7.9.3.1.101 Additional general requirements	10
201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....	11
201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	11
201.9.6.2.1.101 Additional requirements for audible acoustic energy.....	11
201.10 Protection against unwanted and excessive radiation HAZARDS	13
201.11 Protection against excessive temperatures and other HAZARDS	13
201.11.1.2.2 APPLIED PARTS not intended to supply heat to a PATIENT.....	13
201.11.6.4 Leakage	13
201.11.8 Additional requirements for interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT	14
201.12 Accuracy of controls and instruments and protection against hazardous outputs	14
201.12.1 Accuracy of controls and instruments	14
201.12.1.101 Stability of static AIRWAY PRESSURE ACCURACY (long-term accuracy).....	14
201.12.1.102 Stability of dynamic AIRWAY PRESSURE ACCURACY (short-term accuracy)	15

This is a preview of "ISO 80601-2-70:2015". [Click here to purchase the full version from the ANSI store.](#)

201.12.1.102.1	CPAP mode.....	15
201.12.1.102.2	Bi-LEVEL POSITIVE AIRWAY PRESSURE mode.....	17
201.12.1.103	Maximum flowrate	19
201.12.4	Protection against hazardous output.....	20
201.12.4.101	Measurement of AIRWAY PRESSURE.....	20
201.12.4.102	MAXIMUM LIMITED PRESSURE PROTECTION DEVICE.....	20
201.12.4.103	CO ₂ rebreathing.....	20
201.13	HAZARDOUS SITUATIONS and fault conditions	21
201.14	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS).....	21
201.15	Construction of ME EQUIPMENT	21
201.15.101	Mode of operation.....	21
201.16	ME SYSTEMS	21
201.17	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS.....	21
201.17.101	Additional requirements for electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	21
201.101	BREATHING GAS PATHWAY connectors	21
201.101.1	General	21
201.101.2	Other named ports	22
201.101.2.1	PATIENT-CONNECTION PORT	22
201.101.2.2	GAS OUTPUT PORT	22
201.101.2.3	FLOW-DIRECTION-SENSITIVE COMPONENTS.....	22
201.101.2.4	Ancillary port.....	22
201.101.2.5	Monitoring probe port	22
201.102	Requirements for the BREATHING GAS PATHWAY and ACCESSORIES	23
201.102.1	General	23
201.102.2	Labelling.....	23
201.102.3	Humidification.....	23
201.102.4	BREATHING SYSTEM FILTER (BSF)	23
201.103	FUNCTIONAL CONNECTION	23
201.103.1	General	23
201.103.2	FUNCTIONAL CONNECTION to support remote supervision	23
201.104	Training.....	24
202	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests.....	24
202.4.3.1	Compliance criteria	24
202.5.2.2.1	Requirements applicable to all ME EQUIPMENT and ME SYSTEMS.....	24
202.8.1.101	Additional general requirements	24
206	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability	25
208	Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.....	25
211	Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	25
ANNEX C (informative)	Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS.....	26

This is a preview of "ISO 80601-2-70:2015". [Click here to purchase the full version from the ANSI store.](#)

Annex D (informative) Symbols on marking	30
Annex AA (informative) Particular guidance and rationale	31
Annex BB (informative) Data interface requirements	35
Annex CC (informative) Reference to the Essential Principles	39
Bibliography	41
Alphabetized index of defined terms used in this particular standard	43

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/IEC 80601-2-70 was prepared by a joint working group of Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment* and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electrical equipment*.

This first edition of ISO 80601-2-70 cancels and replaces the second edition of ISO 17510-1:2007. This edition of ISO 80601-2-70 constitutes a technical revision of ISO 17510-1:2007 and includes an alignment with third edition of IEC 60601-1 and IEC 60601-1-11.

The most significant changes are the following modifications:

- identification of ESSENTIAL PERFORMANCE for SLEEP APNOEA BREATHING THERAPY EQUIPMENT and its ACCESSORIES;

and the following additions:

- tests for therapy performance; and
- new symbols.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS TYPE.

In referring to the structure of this standard, the term

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- "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- "subclause" means a numbered subdivision of a clause (e.g. 201.7.1, 201.7.2 and 201.7.2.1 are all subclauses of Clause 201.7).

References to clauses within this standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;
- "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

The attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication not be adopted for mandatory implementation nationally earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

Introduction

Sleep apnoea is a chronic medical condition where the PATIENT repeatedly stops breathing during sleep. These episodes typically last 10 s or more and cause the oxygen levels in the blood to drop. It can be caused by obstruction of the upper airway (obstructive sleep apnoea or OSA) or by a failure of the brain to initiate a breath (central sleep apnoea).

NOTE SLEEP APNOEA BREATHING THERAPY EQUIPMENT is intended for the treatment of obstructive sleep apnoea and not central sleep apnoea.

Sleep apnoea, if untreated, can cause and worsen other medical conditions, including hypertension, heart failure and diabetes¹.

Hypopnoea refers to a transient reduction of airflow, often while the PATIENT is asleep, that lasts for at least 10 s, shallow breathing, or an abnormally low respiratory rate. Hypopnoea is less severe than apnoea. It also results in decreased air movement into the lungs and can cause oxygen levels in the blood to drop. It is commonly due to partial obstruction of the upper airway. [16]²

Awareness of the RISKS associated with sleep apnoea has grown significantly. As a result, the use of SLEEP APNOEA BREATHING THERAPY EQUIPMENT to treat both sleep apnoea and hypopnoea has become common.

This document covers BASIC SAFETY and ESSENTIAL PERFORMANCE requirements needed to protect PATIENTS in the use of this ME EQUIPMENT.

ISO 80601-2-70 covers SLEEP APNOEA BREATHING THERAPY EQUIPMENT for PATIENT use. ISO 17510 applies to MASKS and ACCESSORIES used to connect SLEEP APNOEA BREATHING THERAPY EQUIPMENT to the PATIENT. Figure AA.1 shows this diagrammatically.

¹ source: http://sleepdisorders.about.com/od/glossary/g/Sleep_Apnea.htm

² Figures in square brackets refer to the Bibliography.